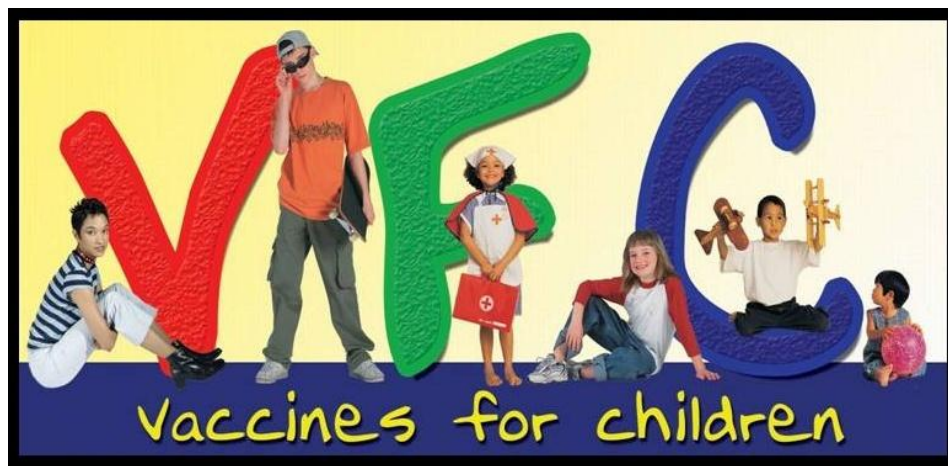


Arizona Vaccines for Children (VFC) Program



Operations Guide 2014



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Vaccines for Children Program

Welcome to the Arizona Vaccines for Children (VFC) program. The Arizona VFC Operations Guide has been prepared by the Arizona Department of Health Services, Arizona Immunization Program Office to provide information to enrolled providers to ensure compliance with federal and state VFC guidelines regarding safe handling, administration, and reporting of VFC vaccines. Recommendations from CDC and the American Academy of Pediatrics are included. We wish to thank CDC staff who have advised and assisted us in the preparation of the Guide.

If you have questions regarding this guide, please call the Vaccine Center at (602) 364-3642.

To all VFC providers, we extend our thanks for immunizing Arizona's children.

Background

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. The program was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC Program allows the Centers for Disease Control and Prevention (CDC) to buy vaccines at a discount from the manufacturers and distribute them to state health departments and certain local and territorial public health agencies, which in turn distribute them at no charge to private physician offices and public health clinics registered as VFC providers.

The VFC Program represents an unprecedented approach to improving vaccine availability nationwide by making federally-purchased vaccine available to both public and private immunization providers. Over the past 20 years, the VFC program has become increasingly recognized for its success in raising immunization coverage rates among high-risk children and reducing disparities in access to health care. The VFC Program has also helped reduce physician referrals for immunizations to public clinics.

Highlights

The VFC Program...

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers in all states, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the commonwealth of the Northern Mariana Islands;
- Provides vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) through passage of VFC resolutions;
- Saves parents and enrolled providers out-of-pocket expenses for vaccine;
- Provides cost savings to states through bulk purchase of vaccines at lower prices using CDC's contracts and eliminates state-to-state variations in price;
- Eliminates or reduces vaccine cost as a barrier to vaccination of eligible children; and
- Reduces the practice of referring children from the private sector to the public sector for vaccination.

Excerpted from the Federal VFC Operations Guide

Definitions and Acronyms Used in this Guide

Aseptic - The absence of microorganisms. Free from infection or septic material; also sterile.

Attenuated - Weakened or reduced

Cold Chain - A temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range. It is used to help extend the shelf life and viability of vaccines.

Diluent - A substance used to dilute. In vaccine use, diluent is used to reconstitute lyophilized (powder) vaccine. Diluents may be sterile water, sodium chloride, or other components. Only the diluent provided with the vaccine should be used with that vaccine.

Electronic Medical Record (EMR) - A specialized medical information software application which electronically documents patient medical information.

Eligible - A patient who meets the criteria for participation.

Inactivated - Killed; cannot replicate, is not infectious and cannot cause disease.

Reconstitution - Restoration to original form of a substance previously altered for preservation and storage.

Restitution - Recompense for lost, wasted, expired or spoiled VFC vaccines due to provider negligence.

Vaccine Coordinator - The staff person in the provider's office who is the primary administrator and contact person for the management of vaccines.

Viable - Capable of living; in vaccines, the state in which vaccines are efficacious.

Vial- A small bottle, usually of glass.

Wastage - Wasteful or avoidable loss. VFC vaccines that are spoiled, expired, or lost may be billed to the provider.

Definitions and Acronyms Used in this Guide

Vaccine Abbreviations

DT	Diphtheria, Tetanus vaccine (Pediatric) <7years of age
DTaP	Diphtheria, Tetanus, acellular Pertussis
DTaP/HepB/IPV	Diphtheria, Tetanus, acellular Pertussis/ Hepatitis B/Polio
DTaP/Hib/IPV	Diphtheria, Tetanus, acellular Pertussis/ <i>Haemophilus influenzae</i> type b/Polio
DTaP/Polio	Diphtheria, Tetanus, acellular Pertussis/Polio
I POL	Inactivated Polio Vaccine (also known as IPV)
LAIV	Live attenuated influenza vaccine
HBIG	Hepatitis B Immune Globulin (hospitals only)
Hep A	Hepatitis A
Hep B	Hepatitis B
HepB/Hib	Hepatitis B and <i>Haemophilus influenzae</i> type B
Hib	<i>Haemophilus influenzae</i> type B
HPV	Human Papillomavirus – 4 or 2 valent
IG	Immune Globulin
LAIV	Live Attenuated Influenza Vaccine
MCV4	Meningococcal Conjugate Vaccine 4 valent
MCV4/Hib	Meningococcal Conjugate Vaccine 4 valent + <i>Haemophilus influenzae</i> type B
MMR	Measles, Mumps, Rubella
MMRV	Measles, Mumps, Rubella + Varicella
PCV 13	Pneumococcal Conjugate Vaccine – 13 valent (6 weeks-5 years and 6-18 years if high risk)
PPV 23	Polysaccharide Pneumococcal Vaccine – 23 valent (2-18 years - <u>high risk only</u>)
Rota	RotaVirus vaccine 5 valent or 1 valent (ages 6 weeks through 32 weeks)

QIV	Quadrivalent Influenza Vaccine
Tdap	Tetanus, diphtheria, acellular pertussis (7–18 years)
Td	Tetanus Diphtheria Vaccine (Adult) >7 years of age only
TIV	Trivalent Inactivated Influenza vaccine
Varicella/VAR/VZV	Varicella (chickenpox)

Chapter 1: VFC PROGRAM GUIDELINES

Eligibility Requirements

- ✓ VFC vaccines can only be given to children ages 0 through 18 years of age that meet the eligibility requirements
- ✓ VFC Eligibility Screening must occur at every visit.
- ✓ VFC providers must provide a copy of the Vaccine Information Statement to patients for each vaccine given.

Eligibility Screening

- ✓ Prior to administering VFC vaccines, each patient must be screened at every visit for VFC eligibility to determine if they are eligible to receive VFC vaccines. If the eligibility status has changed since the previous visit, the new status should be documented by copying the child's new AHCCCS or other insurance card. The child's eligibility may be determined by asking the parent/guardian to complete a *Patient Eligibility Screening Record* (Exhibits #E1A & E1B), and note the eligibility on the *Childhood/Adolescent Immunization Administration Record* (Exhibit #E2)
- ✓ Document the screening information on the Immunization Administration Record, the Patient Eligibility Screening Form or electronic medical record (EMR) so you can retrieve this information for VFC Program reports.
- ✓ **You are not required to verify the patient's response to the screening questions.**
- ✓ Keep the eligibility screening record for six (6) years from the date of the last visit. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
- ✓ If using electronic records, keep the eligibility screening information in the patient's electronic medical record or in a separate database. This information must include the date(s) the patient was screened; keep the eligibility screening information in the database for six (6) years from the date of the last visit.

Eligibility Criteria

Children **birth through 18 years of age** who meet at least one of the following criteria on the day the vaccine is administered are eligible to receive VFC vaccine.

Arizona VFC/KidsCare Eligibility Categories	
Medicaid	A child whose health insurance is provided by the Arizona Health Care Cost Containment System (AHCCCS)
Un-insured	A child who has no health insurance coverage
American Indian / Alaska Native	As defined by the Indian Health Services Act (25 U.S.C. 1603)
Under-insured*	Underinsured means the child has health insurance, but it <ul style="list-style-type: none">• doesn't cover vaccines, or• doesn't cover certain vaccines, or• covers vaccines but has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount is reached, the child is then eligible to receive VFC vaccines.
KidsCare	State-funded insurance program – these children are considered insured and should receive designated KidsCare vaccines.

*If you have not been notified by the Arizona Department of Health Services, Immunization Program Office that you are an approved deputized provider, beginning July 1, 2013, you do not have authority to vaccinate "Underinsured" children. If you are not deputized, please refer all "Underinsured" children to an approved deputized VFC provider office. Deputized providers are listed by county at <http://www.azdhs.gov/phs/immunization/documents/vaccine-policy-changes/underinsured-referral-locations.pdf> . (Also Exhibit 21) Additionally, underinsured children are eligible to receive VFC vaccines through a Federally Qualified Health Center (FQHC aka CHC), a Rural Health Center (RHC) or a County Health Department.

VFC Provider Requirements

- ✓ Providers are required to comply with the appropriate immunization schedule, dosage, and contraindications established by the Advisory Committee for Immunization Practices (ACIP) in VFC resolutions and included in the VFC program unless (a) in the provider's medical judgment and in accordance with accepted medical practice, it is deemed such compliance is medically inappropriate, or (b) the particular requirements contradict the

laws in Arizona pertaining to acceptable exemptions. ACIP VFC Resolutions are available at <http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm>.

- ✓ **Eligibility is not generally retroactive.** Contact the VFC Program if you discover that a child was actually VFC eligible on the date of service but was treated as an ineligible child. In certain circumstances, VFC may be able to replace private stock vaccine with VFC vaccine.
- ✓ An administration fee, not to exceed \$21.33 per immunization, may be charged to non-Medicaid patients. \$21.33 is the maximum fee set by the regional Centers for Medicare and Medicaid Services (CMMS, formerly HCFA) for Arizona. For those children that are Medicaid eligible, please contact your Medicaid Health Plan for specific requirements and rates for billing or go to <http://www.azahcccs.gov/commercial/ProviderBilling/rates/PCSrates.aspx> for more information. **Note: This rate will only be effective during the 2013 and 2014 calendar year.**
- ✓ You may charge patients an administration fee, but if they are unable to pay this fee it must be removed from their bill. Sending these bills to collections is not acceptable.
- ✓ **No VFC eligible patient may be denied vaccine for failure to pay an administration fee.**
- ✓ Failure to waive administration fees according to VFC Program policy could be considered fraud and abuse (see chapter 12 of this manual for more information on fraud and abuse).
- ✓ Each dose of VFC vaccine administered must be:
 - a Documented in the permanent medical record by lot number and manufacturer,
 - b. Reported to the Arizona State Immunization Information System (ASIIIS) Vaccine Order Management System (VOMS) **within 30 days of administration** and should include the lot number and expiration date (ARS 36-135; ARS 36-674; R-9-6-701-707; R9-5-304-304-305)
- ✓ VFC records must be accurate and complete.
- ✓ The following medical protocols must be up-to-date and accessible to all staff who administer vaccines:
 - a. Current CDC Recommended Immunization Schedule
 - b. Vaccine Contraindications/Precautions
 - c. Administration Techniques
 - d. Emergency Vaccine Protocols
- ✓ Only properly trained individuals should administer vaccines.

- ✓ Providers must provide ongoing education and training in the following areas:
 - a Current immunization recommendations should be provided to staff that prepare and administer vaccines.
 - b Train any provider staff involved in receipt of vaccine deliveries to immediately open, inspect and store vaccines upon delivery.
 - c Ensure all staff with vaccine management responsibilities are trained on proper vaccine storage and handling procedures.
 - d Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation on proper vaccine storage and handling procedures.
- ✓ Providers must maintain training records for staff. Documentation must include the staff member's name and date of training.
- ✓ Vaccines supplied by VFC must be identified, labeled, and stored separately from privately purchased vaccines. Contact the Vaccine Center for VFC labels for VFC vaccines.
- ✓ *Vaccine Adverse Event Reporting System (VAERS)* forms must be available and adverse events must be reported promptly and accurately (Exhibit E3). VAERS forms may be obtained by calling 1-800-822-7967 or visit www.vaers.org . Paper copies of VAERS reports should be kept for a minimum of 6 years (For more information on VAERS, see chapter 13 and Exhibit 3).
- ✓ Providers are required to participate in the VFC program compliance site visits including unannounced visits and other educational opportunities associated with VFC program requirements.
- ✓ ***Vaccine Information Statement (VIS)***
According to federal law, you must provide a current Vaccine Information Statement (VIS) every time a patient receives a vaccine and document the publication date of the VIS and the date it was given to the patient in the patient's medical record. VISs are CDC fact sheets that inform vaccine recipients, or their parents or legal representatives, of the benefits and risks of a vaccine. (Exhibit 4)

Give a VIS (either paper or electronic) to the patient before administering each dose of vaccine.

Let the patient keep a paper copy of the VIS, or if they prefer to download the VIS onto a mobile device, direct them to CDC's patient download webpage (www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm) during the visit and make sure they have a chance to have their questions answered. Give them a phone number to call in case of any questions or unexpected symptoms after receiving a vaccine.

When possible, provide the VIS in the person's native or preferred language. Translated VISs are available on the web at no charge at www.cdc.gov/vaccines/pubs/vis.

It is not necessary to have the patient sign anything to show they have received the VIS, unless your practice requires this.

Document the publication date of the VIS, located on the bottom corner of each VIS, in the patient's medical record and the date the VIS was given to the patient.

It is acceptable to provide a VIS before the immunization visit (e.g., by giving the patient a copy to take home during a prior visit, or telling them how to download or view a copy from the internet). We encourage this when possible. Patients must still be offered a copy (it may be a laminated copy) to read during the immunization visit, as a reminder, and a copy to take home.

Private Primary/Medicaid (AHCCCS) as Secondary Insurance

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

Option 1:

A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.

In most health care situations, Medicaid is considered the “payer of last resort.” This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid, the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

Please note: If the state Medicaid agency rejects a claim for a vaccine administration fee for a child with Medicaid as secondary insurance, stating the claim must first be submitted to the primary insurance for payment, please notify the Arizona Immunization Program Office so that we can notify the Arizona State Medicaid Office.

Considerations regarding this option:

- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

Option 2:

A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

If the primary insurance pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee up to the amount Medicaid pays for the administration fee.

If the primary insurer denies payment of vaccine and the administration fee, the provider may replace the private-purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC *borrowing form.

Considerations regarding this option:

- The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- The deciding factor on which vaccine inventory to use should be based on what will be most cost effective for the family.
- The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or for an administration fee.

***Please contact the VFC program to receive a copy of the VFC borrowing form.**

Chapter 2: ARIZONA VFC SUPPLIED VACCINES

Arizona VFC Vaccine Choice Policy

All childhood vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are available through the Arizona Immunization Program Office (AIPO), Vaccines for Children (VFC) program. Therefore, VFC providers with a product preference may choose a particular brand as long as it is available through the VFC program. VFC vaccines may be ordered through the Vaccine Order Management System (VOMS) in the Arizona State Immunization Information System (ASIS).

The Vaccine Center will make every attempt to honor provider choice whenever possible, but the following situations might result in limited brand choice:

- ✓ Manufacturing and distribution product availability or shortage;
- ✓ Influenza vaccine because the manufacturing and distribution systems established by vaccine manufacturers and the Centers for Disease Control and Prevention (CDC) for influenza vaccines requires significant planning to avoid delays
- ✓ New or changing vaccines may not be available immediately upon approval by the VFC program due to procurement processes or due to technical changes or updates to ASIS that require planning, clinical review and implementation by technology staff.
- ✓ Removal of vaccines from availability through the Vaccine Center at the discretion of the Vaccine Center Manager who has such authority.

If a brand chosen by a provider is not available (such as a supply shortage), Vaccine Center staff may take the following action under the authority and approval of the Vaccine Center Manager:

- ✓ If an identical vaccine is available, the alternate brand may be shipped without notification (e.g., Pedvaxhib® and Acthib®). Providers are expected to make use of the equivalent vaccine to the best of their abilities until vaccine supplies normalize.
- ✓ If a similar, but not equivalent vaccine is available, the provider will be asked to approve a replacement before any vaccine is shipped (e.g., Cervarix® and Gardasil®).
- ✓ If a combination vaccine becomes unavailable, the provider will be asked to approve a shipment of individual antigen equivalents before the order is placed with CDC.

The Vaccine Center will honor provider preference for packaging (e.g., syringes vs. vials) whenever possible. If syringes become unavailable for an extended period of time, the Vaccine Center will ship

vials without notification to the provider. If vials become unavailable for an extended period of time, the Vaccine Center will ship syringes to providers ordering less than 50 doses of vaccine in vials. Providers with vial orders greater than 50 must approve a shipment of syringes as a replacement before the order is placed with CDC.

Anytime a provider chooses to utilize a different brand of vaccine, the physician bears the responsibility for using all remaining doses of the “old” vaccine before the expiration date, or safely transferring that vaccine to another active VFC provider. Allowing a vaccine to expire because the provider has chosen to change brands will be considered a failure to properly monitor vaccine, and that provider will be required to replace those expired doses from the Vaccine Center.

VACCINES SUPPLIED BY THE ARIZONA VFC PROGRAM

Vaccine	Brand Name	Manufacturer	Type	# Doses & Indication
DTaP Diphtheria, Tetanus, acellular Pertussis	Infanrix® Daptacel®	GlaxoSmithKline (GSK) sanofi-pasteur	Inactivated Inactivated	5 doses 2, 4, 6, 15-18 mos. & 4-6 yrs 2, 4, 6, 15-18 mos. & 4-6 yrs
DTaP/HepB/IPV Diphtheria, Tetanus, acellular Pertussis/Hepatitis B/Inactivated Polio Vaccine	Pediarix®	GSK	Inactivated	3 doses 2, 4 & 6 months
DTaP/HibB/IPV Diphtheria, Tetanus, acellular Pertussis/ <i>Haemophilus influenzae</i> type b/Inactivated Polio Vaccine	Pentacel®	Sanofi-Pasteur	Inactivated	4 doses 2, 4, 6 & 15-18 mos
DTaP/IPV Diphtheria, Tetanus, acellular Pertussis/Inactivated Polio Vaccine	Kinrix®	GSK	Inactivated	1 dose 4-6 yrs - for 4 th dose of polio & 5 th dose of DTaP <u>ONLY</u>
Hib <i>Haemophilus Influenzae</i> type b	ActHib®	Sanofi Pasteur	Inactivated	4 doses 2, 4, 6, 15-18 mos.
	PedvaxHIB®	Merck	Inactivated	3 doses 2, 4, 15-18 mos
PCV13 Pneumococcal conjugate vaccine 13 valent	Prevnar®	Wyeth	Inactivated	4 doses 2, 4, 6, 15-18 mos.
PPV23 Pneumococcal Polysaccharide Vaccine 23 valent	Pneumovax 23®	Merck	Inactivated	1-2 doses 2-18 yrs for high risk <u>only</u>
Rota Rotavirus	RotaTeq® (RV5) Rotarix® (RV1)	Merck GSK	Live, oral Live, oral	3/2 doses 2, 4 & 6 mos 2 & 4 mos
Polio	IPOL®	Sanofi-Pasteur	Inactivated	4 doses 2, 4, 6, mos. & 4-6 yrs
Hep B Hepatitis B	Recombivax B® Engerix B®	Merck GSK	Inactivated Inactivated	3 doses 0 (birth), 2, 6 mos 0 (birth), 2, 6 mos
Hep A Hepatitis A	Vaqta® Havrix®	Merck GSK	Inactivated Inactivated	2 doses between 12-24 mos 12-24 mos

MMR Measles, Mumps, Rubella	MMRII®	Merck	Live, attenuated	2 doses 12-15 mos & 4-6 yrs
VAR Varicella	Varivax®	Merck	Live, attenuated	2 doses 12-15 mos & 4-6 yrs
MMR-V Measles, Mumps, Rubella + Varicella	ProQuad®	Merck	Live, attenuated	2 doses 15-18 mos & 4-6 yrs
Td Tetanus Diphtheria	Tenivac™	Sanofi-Pasteur	Inactivated	1 dose 7 yrs & older
Tdap Tetanus, diphtheria, acellar pertussis	Adacel® Boostrix®	Sanofi-Pasteur GSK	Inactivated Inactivated	1 dose 11-64 years 10-64 years Can be administered as young as 7 yrs
HPV Human Papillomavirus Vaccine 4 valent Human Papillomavirus Vaccine 2 valent	Gardasil® Cervarix®	Merck GSK	Inactivated Inactivated	3 doses 9-18 yrs – females & males 9-18 yrs – females only
MCV4 Meningococcal Conjugate Vaccine 4 valent	Menactra™ Menveo	Sanofi-Pasteur Novartis	Inactivated Inactivated	2 doses 11-12 yrs with a booster at 16 yrs 11-12 yrs with a booster at 16 yrs
Flu Influenza vaccine	Fluzone® Fluarix® FluMist®	Sanofi-Pasteur GSK MedImmune	Quadrivalent Inactivated Inactivated Live attenuated	1 dose annually 6 mos & older 3 yrs & older 2-49 yrs
Biologicals provided under special circumstances				
HBIG Hepatitis B Immune Globulin (birthing hospitals only)				
DT Diphtheria, Tetanus	DT	Sanofi-Pasteur	Inactivated	If 1 st dose given at younger than 12 mos, 4 doses are recommended. If 1 st dose given at 12 mos or older, 3 doses complete the primary series

Chapter 3: PROVIDER ENROLLMENT IN THE VFC PROGRAM

Annual Provider Enrollment

Enrollment in the Arizona VFC Program is simple. Interested health care providers should call the VFC office at (602) 364-3642 to obtain a new provider enrollment packet.

The following criteria will be considered when determining Provider VFC eligibility and enrollment:

- ✓ Provider and provider staff not included on the Office of Inspector General (OIG) List of Excluded Providers
- ✓ Provider(s) signing the Provider Agreement has a valid license to administer vaccines within the awardee jurisdiction
- ✓ Provider has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring capacity

The following information will be required for enrollment into the VFC program.

1. **Provider Agreement** (Exhibit E5) - defines CDC compliance parameters of the VFC program.
 - a **VFC Provider License Information** lists the names, AHCCCS number and medical license number of the provider signing the agreement. The signing provider is responsible to assure all staff within the organization are in compliance with this VFC provider enrollment requirement.
2. **Provider Profile** (Exhibit E6) – provides demographic information of the provider site and identifies the number of children in the practice by eligibility and age group. **The profile numbers must be based on real data, not provider estimates.** This information is important to accurately order vaccines. Providers may submit information from their Medicaid Claims Data, ASIIS, doses administered, provider encounter data, billing systems, or benchmarking. Providers will not be able to obtain this information from the VFC program.
3. **VFC Vaccine Ordering and Arizona State Immunization Information System (ASIIS) User Information and Pledge**– (Exhibit E7 and E8) identifies provider staff who can order VFC vaccine through the Vaccine Ordering and Management System (VOMS) and access the ASIIS database to query, enter and/or edit immunization data. **Each person designated to enter orders into VOMS should have their own unique username and password.**

4. **Refrigerator/Freezer Verification Form** (Exhibit E9) - describes refrigeration requirements for vaccines. For new or returning VFC providers, refrigerator and freezer temperatures must be recorded on a temperature log twice daily for five consecutive days and the temperature log must be submitted prior to receipt of the first VFC vaccine order.
5. Upon receipt of the completed forms by the Vaccine Center, the provider will be assigned a VFC Provider Identification Number (PIN). The provider PIN is assigned to you upon initial enrollment in the Arizona VFC Program and will remain your unique identification number until you request to be inactivated, request a change due to sale of the provider practice, or other change. **Please remember your PIN!** You will be asked for the PIN on all correspondence, orders, and inquiries to the Vaccine Center.

Your VFC Immunization Provider Identification Number (PIN) is:

6. Vaccine Center staff will contact the new provider to schedule an on-site visit to examine the refrigerator/freezer and authorize the receipt of the initial vaccine order, and to train provider office staff in VFC policies and procedures.

VFC Re-enrollment

The Arizona VFC Program requires all providers to re-enroll annually by December 31st. Updates and revisions to the *Provider Profile* should be done more often if there are changes in the practice during a current enrollment year. Annual re-enrollment forms are available on the Arizona VFC website at <http://azdhs.gov/phs/immunization/vaccines-for-children/> to all VFC providers in September or October and must be returned to the VFC office by November 30th of each year to ensure continued shipment of vaccines unless otherwise stated by the Arizona Immunization Program Office. **Providers who fail to re-enroll will automatically be inactivated on January 1st and vaccine ordering and delivery will be discontinued.** It will then become the provider's responsibility to return all remaining VFC vaccines and equipment to the Arizona VFC program. Failure to return the vaccines will result in the provider receiving an invoice for the replacement of VFC vaccines based on their current inventory in ASIIS.

Chapter 4: ARIZONA STATE IMMUNIZATION INFORMATION SYSTEM (ASIIS)

ASIIS REQUIREMENTS

- ✓ All doses administered must be manually entered into ASIIS or reported electronically. Paper reporting will not be accepted.
- ✓ Doses administered must be reported to ASIIS within 30 days.
- ✓ All doses administered to children 0 through 18 years of age must be reported to ASIIS.
- ✓ User Information must be updated quarterly.
- ✓ Providers must adhere to the requirements in the ASIIS Confidentiality Policy.

What is ASIIS?

The Arizona State Immunization Information System (ASIIS) is an immunization registry designed to capture immunization data on individuals throughout the state. The registry serves as a repository for the reported data. In this capacity, the registry provides a valuable tool for the management and reporting of immunization information to public health professionals, private and public healthcare providers, parents or guardians.

State Law Concerning ASIIS

Arizona Revised Statutes (A.R.S. §36-135) requires all providers to report all vaccines they administer to children birth through 18 years of age to ASIIS. Failure to report is a Class 3 misdemeanor.

ASIIS Paper Reporting

Paper reporting can no longer be used to report doses administered to ASIIS. All doses must be reported electronically. Please contact the ASIIS hotline at 877-491-5741 for further information.

ASIIS Electronic Reporting

ASIIS was recently upgraded and all DTT upload processes and flat file transfers must be transitioned to a different reporting method. All electronic reporting providers will transition to an HL7 upload process. We realize not all providers are able to easily

migrate to the current HL7 format and/or many providers are in the process of upgrading to the current HL7 version. An alternate method for uploading your data into ASIIS is available until your EHR system is able to send HL7 data. Please send an email to ASIIS_Group1@azdhs.gov for more information.

The following information must be included for all reporting methods:

IRMS	Facility ID	Medical Record #	Patient Last Name
Patient First Name	Patient DOB	Patient Gender	Patient Address
Patient City	Patient State	Patient Zip Code	Patient Phone Number
Guardian First Name	Guardian Last Name	Relationship	Administration Date
CVX Code	CPT Code	Lot Number	Expiration Date
Manufacturer	VFC Status	Funding Source (public or private)	

ASIIS Contact Information

Call the ASIIS Hotline Toll Free 1-877-491-5741 or, in the Phoenix area, (602) 364-3899 or visit the ASIIS website at <https://www.asiis.state.az.us/>

Note: *VOMS is an application within ASIIS. VFC vaccine is ordered through VOMS.*

Chapter 5: VACCINE ORDERING AND DOCUMENTATION

VACCINE ORDERING REQUIREMENTS

- ✓ Temperatures must be recorded twice daily.
- ✓ Temperature logs must be submitted to the Arizona VFC program monthly, whether you are ordering or not ordering.
- ✓ Providers must order vaccine at least annually and maintain appropriate inventories

Vaccine Ordering Process

The Arizona Vaccine for Children Program (VFC) has implemented a vaccine ordering system to assist VFC providers in managing their VFC vaccine inventories, decrease wasted vaccines due to overstock, and spread out vaccine orders over the course of each month.

VFC providers are assigned to a specific week during the month to place orders and are required to adhere to the following schedule when ordering VFC vaccine monthly, quarterly or whenever needed. Please contact the Vaccine Center if you are unable to place your order during the specified timeframe.

Order Frequency	Provider PIN Ending digit
1 st and 2 nd week of the month	0 - 4
3 rd and 4 th week of the month	5 - 9

Example:

If your VFC PIN ends in 0 – 4, you will order the 1st and 2nd weeks of the month.

If your VFC PIN ends in 5 – 9, you will order during the 3rd and 4th weeks of the month.

Note: Providers are always required to reconcile their inventory in VOMS before placing an order.

Placing an Online Vaccine Order

1. Use the online Vaccine Order Management System (VOMS) in ASIIS to place an order for VFC Vaccine. An ASIIS Username and Password is required to access VOMS. To obtain a new ASIIS User Name and Password, go to www.azdhs.gov/phs/asiis/enrollment.htm and complete the ASIIS Enrollment Application and User Agreement. There are detailed instructions located on the enrollment form on how to send the form to ASIIS. If you are unable to obtain the form from the ASIIS website, please call the ASIIS Hotline at 602-364-3899 or 1-877-491-5741.

For step-by-step instructions on how to place a VOMS order, see the *Vaccine Ordering Management System Manual (Exhibit E10)*.

2. Prior to placing a VOMS order, collect your *Arizona VFC Patient Immunization Log(s)* (Exhibit E11) and place the total number of doses of each vaccine administered in the row marked, "Page Totals." Make sure the form is complete. VFC providers are required to keep the *Arizona VFC Patient Immunization Logs* on site for six (6) years. Please **do not fax or mail** the *Arizona VFC Patient Immunization Logs* to the Vaccine Center.
3. To ensure you have the data necessary to complete the online VOMS order, complete the *VFC VOMS Worksheet* (Exhibit E12) prior to placing your online order. Please follow the instructions below:
 - a. Enter the totals from the immunization log(s) for each vaccine administered into the column marked "doses administered" on the *VFC VOMS Worksheet* if there is more than one log, total all pages before entering the total "doses administered". These numbers should be for the time period stated at the top of the order form.
 - ✓ Count the inventory (number of doses of each vaccine) in the refrigerator(s) and freezer(s) and enter the total numbers on the *VFC VOMS Worksheet* in the column marked "Doses on Hand." Log on to ASIIS to access VOMS and follow the instructions in the VOMS Manual. Verify the data you recorded on the *VFC VOMS Worksheet* against the information that is in ASIIS.
 - b. **Compare this information to what is in ASIIS in the ASIIS/VOMS reconciliation screen. Please be sure to choose the correct reason from the drop down menu in your reconciliation screen for vaccines that are no longer in your inventory.**

Note: VFC vaccine inventory must be recorded for each VFC vaccine, not just for the vaccines you are ordering.

4. Providers are encouraged to keep a 4-6 week supply of vaccine on hand based on the provider's anticipated VFC eligible population and previous order history. If a provider must order more than a 4-6 week supply, a comment must be placed on the order screen in VOMS stating the reason for ordering additional vaccine. It will be at the discretion of the Vaccine Center to approve or deny the order.
5. Collect the *Refrigerator/Freezer Temperature Log(s)* (Exhibit E13). Email or Fax the temperature logs to the Vaccine Center. **Do not mail** the *Arizona VFC Patient Immunization Logs* to the Vaccine Center but retain them on site for six (6) years. If temperature logs are not received by the Vaccine Center within four (4) days of placing the order, vaccine orders will be cancelled.

The Vaccine Center uses comments in ASIIS/VOMS to provide direct communication to individual provider offices regarding their orders. It is important to frequently check VOMS "comments" to determine the status of your order.

Note: Telephone orders are not accepted (except for Pediatric DT)

Emergency Vaccine Orders

Emergency vaccine orders should not occur frequently. Providers are encouraged to keep a 4-6 week supply of vaccine on hand based on the provider's anticipated VFC eligible population and previous order history. If necessary, all healthcare providers (regardless of order frequency) will be able to place "special" orders with approval of the Vaccine Center. Reasons for special orders can include, but are not limited to:

- ✓ New healthcare provider
- ✓ Outbreak
- ✓ Health fair
- ✓ Special initiative
- ✓ Special clinic
- ✓ Wastage/improper storage
- ✓ Power outage/equipment failure (after 5 days of temperatures within normal limits)
- ✓ Natural disaster
- ✓ Insufficient inventory (**This is only in the event of an unforeseen circumstance, provider should be ordering vaccines based on current patient population**)

It will be important for VFC providers to ensure they add the reason they are requesting an additional order outside of their normal ordering schedule to the comments section in ASIIS/VOMS.

Order Delays or Cancellations

Orders will be denied or placed on hold for the following reasons:

- ✓ Temperature log is missing or the temperatures are out of range
- ✓ Number of “doses administered” is missing
- ✓ Number of doses on hand (inventory) is missing
- ✓ Inventory reconciliation has not been completed in VOMS

This information will be posted in VOMS within the comments section in your order screen.

Backorders

If the Vaccine Center is waiting on vaccines to be released by CDC, we will place the specific vaccines we are waiting on into backorder status and leave a comment for you in your order. There is no need to re-order that vaccine. We will release it once the vaccine is available from CDC.

VOMS Comments

The Vaccine Center uses comments in ASIIS/VOMS to provide direct communication to individual provider offices regarding their orders. It is important to frequently check VOMS “comments” within your order screen to determine the status of your order. If you have questions, please contact the Vaccine Center at 602-364-3642.

Reporting to ASIIS – Arizona Revised Statue Requirement

Each time a dose of VFC vaccine is administered, the vaccine name, lot number, expiration and manufacturer must be recorded and reported in ASIIS before vaccines are ordered. **Note:** VFC vaccines administered at the provider’s office should not be marked as “historical” in ASIIS. “Historical” classification in ASIIS should only be used to record vaccinations that were administered at another provider’s office.

Per Arizona Revised Statue (A.R.S. §36-135), providers are required to report all vaccine doses administered to children birth through 18 years of age to ASIIS as part of the child’s immunization record.

Temperature Logs

VFC providers are required to scan and email or fax temperature logs to the Vaccine Center monthly, whether or not you are placing a vaccine order.

Temperature logs must include **the date and time the temperature was checked, initials of the person who checked the temperature, and indicate whether the temperature is Fahrenheit or Celsius**. The temperature logs must be received by the Vaccine Center before an order will be approved. Temperature logs should be completed up to the day before the vaccine order is placed. For example if you order vaccine on the 15th of the month, the temperature log should be filled out through the 14th of that month. The Vaccine Center team must ensure that current temperatures in the provider's refrigerator and freezer are within normal limits before an order can be approved.

Scan and email temperature logs monthly to: arizonavfc@azdhs.gov

Or

Fax temperature logs monthly to: Vaccine Center (602) 364-3276 or (602) 364-3232

Note: All correspondence regarding missing information will be added as a message in the comments section on your ASIIS/VOMS order screen. Please regularly check the "comments" section within your order for these messages to avoid order delays or cancellations. **If temperature logs are not received by the Vaccine Center within four (4) business days of placing the order, the VFC Vaccine Order Specialist will enter a comment informing the provider that their vaccine order will be cancelled and a subsequent order will have to be placed by the provider office.**

Note: The ability to electronically submit refrigerator and freezer temperature logs and eligibility via VOMS is in development. VFC providers will be informed when this is ready for use.

Maintaining Vaccine Inventory

When establishing vaccine needs, consider:

- ✓ Vaccine usage patterns (increase orders during July and August for “back-to-school” children);
- ✓ Length of time before the next ordering date;
- ✓ Storage capabilities (do not order more vaccine than you can store and do not order pre-filled syringes if you do not have a large refrigerator – pre-filled syringes take more room than vials);
- ✓ Order enough vaccine to last for approximately 2 weeks past the assigned order schedule to allow for delivery time.

VFC providers must conduct a monthly physical inventory of VFC vaccines. When conducting the monthly inventory, check the expiration dates for all vaccines. Move soon- to-expire vaccines to the front of the refrigerator/freezer so they are used first.

Vaccine Shipments

The Arizona Vaccine Center acts as the coordinating center for federal and state-purchased vaccines in Arizona. Vaccines are routinely shipped from a distribution center to the provider’s office **5 – 10 business days** from the time the vaccine order is placed by the VFC program. If there are any changes to the standard shipping routine, the Vaccine Center will notify the provider.

Once vaccine orders have been received, reviewed and approved by the Vaccine Center, the orders will be transmitted to the distributor (McKesson) who will deliver the vaccines directly to the provider’s office. Providers should expect their vaccine order within 10 – 14 days from the time they place the order. Providers must plan ahead when ordering to allow time for delivery. Orders from McKesson should arrive in provider offices on Tuesdays, Wednesdays or Thursdays.

- ✓ Varicella and MMRV vaccines are shipped directly from Merck Manufacturing. Please allow 2-4 weeks to receive these vaccines.

Receiving VFC Vaccine Shipments

1. Proper handling and temperature maintenance of any vaccine shipment is imperative to maintain the cold chain and vaccine potency. Each provider site is required to have a standard office procedure for receiving vaccine shipments. A VFC vaccine shipment can be worth hundreds or thousands of dollars, proper handling of each dose is critical in preventing unnecessary loss or wastage. If vaccines are improperly handled, they will lose potency and will have to be replaced. See Chapter 7 for more information about Vaccine Management and Accountability.
2. The provider office VFC Coordinator or back up should;
 - a. Notify other office staff that vaccine shipments will be arriving, and
 - b. Instruct front office staff on how to receive and store refrigerated and frozen shipments.
3. Office staff should unpack vaccine immediately, and do the following:
 - a. Receive and sign for vaccine orders placed by **your office only**.
 - b. Open vaccine packages immediately.
 - c. Inspect the packages and vaccines for damage.
 - d. Determine length of time the vaccine was in transit by looking at the packing list
 - e. Compare the vaccine received with the vaccine products that appear on the packing list
 - f. Check temperature indicators enclosed in each container. Notify the Vaccine Center **immediately** if the temperature indicator has changed color, the ice packs are soft, the vaccines are warm or frozen vaccines shipped by Merck are not received within 4 days of the shipping date on the container.
 - g. Review the information provided on the packing slip to ensure:
 - i. the number of doses shipped and the number received are the same;
 - ii. the vaccine expiration dates are the same on the vaccine boxes and the packing slip; and
 - iii. the lot number(s) on the vaccine boxes match the packing slip.
 - h. Remove vaccines from the shipping container and **immediately** store in refrigerator and/or freezer.
 - i. Check the diluents. **Any diluents arriving frozen must not be used**. Call the Vaccine Center immediately.
 - j. Compare your order in VOMS to the vaccine shipment. If there are discrepancies, please appropriately store the VFC vaccines and mark **DO**

NOT USE. Contact the Vaccine Center immediately for further assistance.

- i. Write any shipment discrepancies and/or problems with the vaccine order on the packing slip and fax the slip to the Vaccine Center **within 2 hours of receipt. Do Not call the manufacturer with any VFC vaccine problems.**
 - ii. If you encounter any vaccine shipment problems, call the Vaccine Center immediately– the Vaccine Center staff will determine the appropriate next steps.
4. **It is critical that each VFC provider label and store VFC vaccine separately from private stock vaccines.** VFC vaccine must not be administered to adults, even if the packaging indicates that the vaccine can be used for adults. VFC vaccine is ordered on CDC pediatric vaccine contracts and is not allowed to be used for adults.
 5. Do not fax the packing slip to the Vaccine Center unless there are discrepancies in the shipment.
 6. Carefully examine each Varicella shipment packing slip to determine whether it is VFC or private stock. **The box that contains the Varicella vaccine shipment will not be marked “VFC”**, so be sure to check the shipment before putting it into the freezer. Do not call the Vaccine Center about a missing Varicella shipment until all shipments received in the past month have been checked.
 7. Place a VFC label on all VFC vaccine boxes or mark the boxes “VFC”. Order VFC labels from the Vaccine Center and keep these labels on hand at all times.
 8. ***Frozen Vaccine Storage Requirements (Varicella & MMRV)*** (Exhibit E14) – explains procedures for storing Varicella (chicken pox) and MMRV (Measles, Mumps, Rubella and Varicella) vaccine.

Remember: Unpack vaccine **as soon as the package arrives** in the office and store the vaccines in the refrigerator or freezer depending on the type of vaccine.

Remember: MMR can be stored in the freezer or the refrigerator; **Varicella and MMRV must be stored in the freezer.**

Transferring VFC Vaccine Between Provider Offices

Vaccines are increasingly expensive and are now a large part of any office or clinic's costs. They must be managed closely to avoid unnecessary loss. Every attempt should be made to avoid vaccine wastage and minimize the amount of vaccine allowed to expire. **Excessive vaccine wastage occurring during the calendar year requires restitution from the VFC provider. If the amount of wastage exceeds 5% of doses shipped, the provider will receive an invoice stating the number of VFC doses needing to be replaced.** (See Chapter 7 for Vaccine Wastage Restitution Policy).

Transferring VFC vaccines between provider sites is permitted on occasion. **Please note, CDC does not allow for the use of vaccine depots and therefore provider offices cannot order large quantities of VFC vaccine for re-distribution to their other clinic sites. Please adhere to the following when completing a transfer.**

1. The transferring provider office must contact the Vaccine Center to obtain a current list of available VFC providers in their area. The transferring provider must contact providers on the list to determine if a transfer will be accepted by a provider.
2. Once this occurs, the "sending" provider must complete the transfer in ASIIS to the "receiving" provider
3. The Vaccine Center must approve the transfer in ASIIS before the physical inventory can be transported by the "sending" provider to the "receiving" provider's office.
4. Once the transfer has been approved in ASIIS/VOMS, the "sending" provider will pack the vaccine according to Vaccine Center guidance, and transport the vaccines to the "receiving" provider's office.
5. The "receiving" provider will inspect the vaccines and if there are no issues, accept the vaccine transfer into their inventory through ASIIS/VOMS. Similar to vaccine shipments, ensure the transferred vaccines are immediately placed in the refrigerator and/or freezer.

Providers should contact other providers regarding expiring vaccines **at least three (3) months** prior to vaccine expiration. If your practice has vaccine that will expire soon and you do not think it will be used during that time. Begin contacting other VFC providers who might be able to use the vaccine before it expires.

Note: The provider must contact the Vaccine Center for packing and transport instructions before transporting the VFC vaccines. VFC vaccine may not be shipped to, or stored at, a private residence or a location that is not the provider's office address. **Varicella and MMRV are not allowed to be transferred between providers due to their fragile nature.**

Chapter 6: ORDERING DURING INFLUENZA SEASON

VFC Influenza Process

The Arizona VFC Program places an annual influenza order for publicly funded vaccines with the CDC around February or March each year for the upcoming influenza season. Generally, some of the influenza doses are received at the end of July. However, we do not receive all of the requested doses in July. Unfortunately, we may not receive the vast majority of influenza doses until mid to late August and sometimes even later. This causes delays in the influenza order approval process. The doses that we do receive during that time will be released to providers as quickly as possible.

Providers can expect this type of delay to occur annually with VFC influenza vaccines. When this happens, it does not mean there is a shortage of vaccines. It means the CDC distributor does not have any additional doses available at that time, and as soon as more become available, they will make them available to the Arizona VFC Program and we will release them to the provider offices. When the Arizona VFC program is waiting for the additional doses to be released, your order for the specific influenza vaccines that are unavailable may be placed in a “backordered” status in ASIIS/VOMS by the Arizona VFC program team. This means the influenza doses that you have requested to order are not yet available, but will be later in the season. It is not necessary to place another order if you see your influenza vaccines have been placed in backorder. The Arizona VFC program will make sure you are aware of the delay by communicating this in the comments section of your order screen in VOMS. It will be important for providers to frequently check their comments.

In some instances during the end of influenza season, we may run out of a particular influenza presentation. In most cases we will contact you to inform you of this situation and in some situations we will replace the vaccines (please see the Arizona VFC Choice Policy in chapter 2 of this manual).

Influenza Ordering

Influenza ordering is done through ASIIS/VOMS. Influenza orders can no longer be accepted through the previous paper ordering methods. **Providers should place orders at least once a month to replenish your influenza supply.** Please contact ASIIS/VOMS for assistance on placing an influenza order.

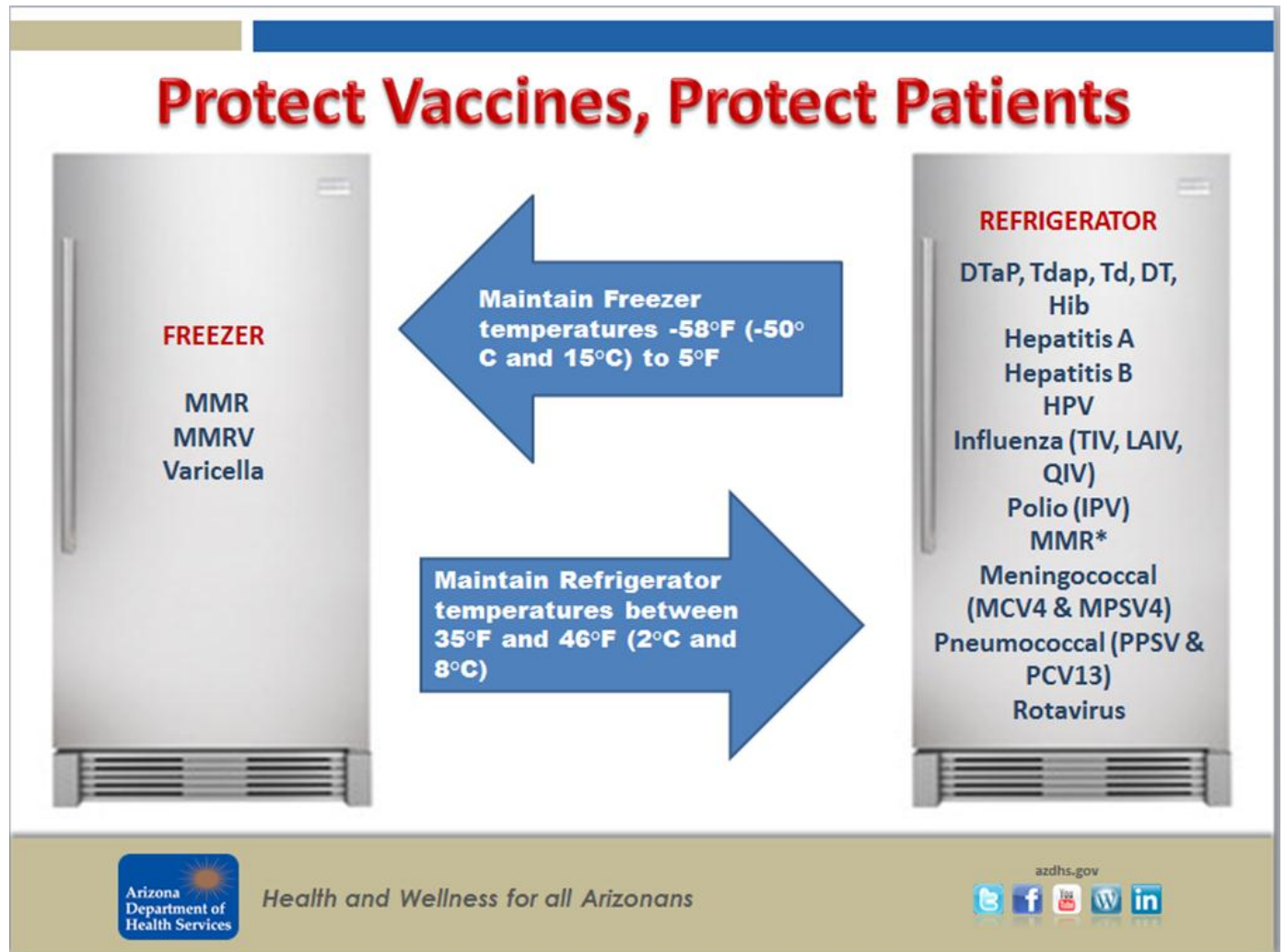
Inventory Reconciliation

When placing a flu vaccine order, you still need to reconcile your inventory. ASIIS/VOMS will not allow the provider to advance to the order screen without reconciling your inventory first.

For additional questions related to VFC Influenza ordering please contact the Arizona VFC Program at 602-364-3642. For technical questions related to ASIIS/VOMS please contact 877-491-5741.

Handle with Care!

If you don't protect your vaccine, it won't protect your patients!



* MMR can be stored in the freezer or the refrigerator

Vaccine Management Requirement

- ✓ Providers must be able to distinguish between private and public purchased vaccine stocks; stocks must be separate.
- ✓ The use of a dormitory or bar-style refrigerator/freezer is not allowed at any time for the storage of VFC vaccines
- ✓ Providers must use a digital thermometer with a biosafe glycol encased probe that will measure liquid temperature. The refrigerators and freezers that store VFC vaccines must have NIST Certified and calibrated thermometers.
- ✓ Providers must have at least one back up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer).
- ✓ Thermometers must be placed in a central area of the storage unit with the vaccines.
- ✓ Providers must maintain a VFC Provider *Vaccine Storage and Handling* plan.
- ✓ Providers must have a primary VFC Coordinator and a backup person.
- ✓ Vaccine wastage must be replaced on a dose for dose basis.

Vaccine management is a broad term intended to describe the storage and handling practices that should be followed by providers.

The Vaccine Cold Chain

The ***cold chain*** is a system or process used to maintain vaccines at optimal conditions. Vaccines must be stored properly from the time they are manufactured until the time they are administered to ensure those who receive the vaccines are protected from disease. Excess heat or cold will reduce vaccine potency and increase the risk that recipients will not be protected. All VFC vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.

Refrigerator/Freezer Equipment

Although a standard-size, two-door, household-type refrigerator with a separate temperature control for each compartment can be used for storing vaccines; **stand-alone commercial units are strongly recommended and are now the acceptable standard for vaccine storage.** The Arizona VFC program does not allow the use of combination refrigerator/freezers with one exterior door and a freezer inside of the refrigeration unit to store Arizona VFC vaccines. This includes “dormitory” or “bar” style units.

The Vaccine Center will only ship varicella vaccine to sites where the refrigerator/freezer used to store vaccine is CDC/VFC approved. The VFC program does not endorse any specific refrigerator/freezer brand or manufacturer, but units used to store VFC vaccine must meet required specifications (Exhibit E9). Please contact the Vaccine Center at 602-364-3642 if you have questions about your refrigerator's ability to properly store vaccines.

Temperature Monitoring Equipment

VFC providers are required to use a thermometer that is calibrated, NIST Certified and has a current certificate of traceability* in each refrigerator/freezer used to store vaccine. Each thermometer must be a digital thermometer with a probe that is placed in a bio-safe, glycol filled bottle to monitor vaccine temperature - not the ambient air inside of the unit. **It is the responsibility of the provider's office to ensure that the thermometer is calibrated and certified annually.** For more information on current calibration standards, please contact the Vaccine Center at 602-364-3242.

CDC and the Arizona VFC Program **strongly recommends** the use of **continuous temperature monitoring systems** (i.e. digital data loggers). These units provide a more accurate reading of actual temperatures than other temperature monitors. Digital Data Loggers provide comprehensive monitoring of temperature excursions to which vaccines may be exposed. They also diminish the need for opening the unit door while conducting routine temperature monitoring.

The data stored in the temperature monitor should be easily downloadable for review. This means that the digital temperature monitoring device should have a detachable probe (kept in the glycol-filled bottle). A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator-caused temperature variability. The recommended digital data logger should also include the following capabilities:

- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)

CDC recommends assessing and documenting minimum/maximum temperatures for each storage unit at the beginning and end of the workday.

***A certificate of traceability confirms that measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST or to another internationally recognized standard agency.**

Back Up Thermometer

VFC providers must have at least one back up thermometer with a current certificate of calibration on hand (not stored in unit). It should be available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.

Thermometer Placement

Because a major risk factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important and required that glycol-encased probes be placed in the same area where the vaccine is stored. For refrigerated vaccines, vaccine and temperature monitors should be located in the part of the refrigerator unit where appropriate temperatures are best maintained.

Maintaining VFC Vaccine Viability

The following tips are to assist in maintaining a safe refrigerator environment and constant temperature for your vaccine supply:

1. Install the refrigerator/freezer away from any heat sources such as direct sunlight, furnaces, or radiators.
2. Keep refrigerator and freezer sections full, but don't overcrowd shelves (allow full air circulation).
3. Add water bottles to the sides and back of the refrigerator to assist in maintaining an even temperature.
4. Open and close door quickly; minimize the time the refrigerator door is kept open.
5. Check frequently to see that there is a tight door seal.
6. Clean condenser coils at the rear of the refrigerator at least two to six times a year to prevent loss of cooling efficiency when coils become insulated with dust.

7. **Always** store vaccines in their original boxes with the lids.
8. Store vaccines on the middle shelves of the refrigerator. **Do not store vaccines in vegetable bins, in the doors, or floor of the unit, or under or near cooling vents in the refrigerator or freezer doors.** The temperatures in these sections do not remain constant. We recommend removing the vegetable bin drawers and replacing them with water bottles.
9. Place ice packs around and on top of the vaccine in the freezer, as if covering it with a blanket.
10. MMR, Varicella, MMRV, Rotavirus, HPV, and MCV4 are extremely sensitive to light. To prevent exposure to light, keep the ends and top of the box closed at all times during storage.
11. If you are using a two door refrigerator, the freezer compartment must be **separate, sealed, and insulated.**
Note: Freezer compartments that are inside the refrigerator **do not** meet VFC and CDC storage requirements and cannot be used at any time for any reason. **These units are called “dorm” style or “bar style” units.**



12. For manual defrost units, defrost the freezer compartment whenever the frost layer is 1/4-inch thickness. Excess frost can prevent a tight door seal.
13. **Do not freeze diluent.** Please see the *How to use Diluents* table in Chapter 7 for correct storage of diluents. The Vaccine Center is unable to ship additional diluents if wasted.
14. Place water bottles throughout storage units in order to:
 - a Stabilize or extend temperatures during a power outage, and

- b. Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions.
- 15. Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front
- 16. Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.
- 17. Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- 18. In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC strongly recommends NOT pre-drawing doses before they are needed.
- 19. In mass vaccination clinics, providers may pre-draw up to 10 doses or use pre-filled syringes.

Refrigerator/Freezer Temperatures

1. **Keep your refrigerator and freezer at appropriate temperatures.**
 - a. Your refrigerator should be kept between 35°F and 46°F (2°C - 8°C).
 - b. Your freezer should be kept between -58°F to +5°F (-50°C and -15°C).
2. Record refrigerator and freezer temperatures twice daily (early morning and at the end of the day) in F **or** C (not both). Providers should not go more than 4 consecutive days without temperature monitoring. If staff will be out of the office longer than 4 consecutive days, it is required that providers contact the Vaccine Center.
3. Maintain a working NIST certified or traceable thermometer in **both** the refrigerator and freezer and check/monitor calibration due date. **It is the provider's responsibility to ensure thermometers are calibrated annually.**
4. The following vaccines **must** be stored at temperatures between 35°F and 46°F (2°C - 8°C) *Fahrenheit to Celsius Conversion Chart* (Exhibit E15). The temperature should never go below 32°F for these vaccines. If the temperature is recorded at or falls below 32°F, notify the Vaccine Center immediately. **Do not**

wait until it is time to place an order to report out of range temperatures to the Vaccine Center. Your VFC vaccines will be wasted and you will be required to replace wasted doses of VFC vaccines.

DT	IPV	HBIG (hospitals) & IG	TD
DTaP	Hepatitis A	Influenza	Tdap
DTaP/HepB/IPV	Hepatitis B	MCV4	
DTaP/Hib/IPV	Hib	PCV13	
DTaP/IPV	HPV	PPV23	

5. The vaccines listed above in #4 should **not** be exposed to temperatures at or below 32° F. **Vaccine will be removed from provider offices if refrigerator temperatures reach 32°F and below**
6. MMR may be stored in either the freezer or the refrigerator. Freeze MMR if you need more refrigerator space. MMR is much less likely to be spoiled if kept in the freezer. MMR must be stored in its original box to protect from light.
7. Varicella and MMRV **must be stored in the freezer**. To prevent light exposure, store Varicella and MMRV in their original boxes, keeping the ends and tops closed at all times.
8. Store ice packs in the freezer to help maintain acceptable temperatures in the event of a power outage.
9. Maintain freezer temperature between -58°F to +5°F (-50°C and -15°C). (See Exhibit 15).
10. Call the Vaccine Center immediately at (602) 364-3642 with any problems with refrigerator and/or freezer temperature controls. Notify the Vaccine Center if the refrigerator or freezer temperatures register out of range, at any time.

Vaccine Storage and Handling Plan

The routine vaccine storage and handling plan must include guidance on routine vaccine management processes/practices.

The minimum required components of VFC Provider Vaccine Storage and Handling Plan includes the following:

- Name of the current primary vaccine coordinator and at least one back-up coordinator

- General operations for the following vaccine storage and handling practices:
 - ✓ Proper vaccine storage and handling practices
 - ◇ Temperature monitoring
 - ◇ Vaccine storage (e.g., equipment, placement)
 - ✓ Vaccine shipping and receiving procedures
 - ✓ Vaccine ordering procedures
 - ✓ Inventory control (e.g., stock rotation)
 - ✓ Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
- Staff training (and documentation of training) on VFC requirements, including proper vaccine storage and handling

Inventory Management

Inappropriate monitoring, handling or administration of vaccine may result in vaccine that does not provide protection. In addition to the best practices listed below, follow the storage and handling instructions contained in the package inserts of each vaccine.

1. VFC providers must assign responsibility for vaccine management to one individual, the VFC Vaccine Coordinator, and one backup person. ***If a provider has multiple clinics, there must be backups at each of those clinics that can answer questions regarding VFC related issues.*** If the VFC Vaccine Coordinator leaves the practice, it is the responsibility of the office manager or medical professional signing the provider profile to ensure that refrigerator and freezer temperatures are checked and recorded twice each day by trained staff and the Vaccine Center notified immediately of any temperature excursions outside the recommended ranges. **Please do not leave this in the hands of untrained staff. Notify the Vaccine Center immediately of any changes.**
2. In addition to monitoring storage conditions, the VFC Vaccine Coordinator or backup should regularly review each vaccine vial for expiration dates placing “short-dated” vaccine (vaccine about to expire) in the front of the refrigerator or freezer for immediate use. Observe the expiration date on each vial of new vaccine shipments; it is possible to receive vaccine that will expire sooner than current vaccines in your inventory.
3. Develop and conduct training for all office staff.
4. Record F or C (must be consistent) refrigerator and freezer temperatures twice daily (early morning and at the end of the day). Refrigerator and freezer

thermometers must be NIST (National Institute of Standards and Technology) Certified or NIST traceable and calibrated.

5. Maintain inventory control records to monitor lot numbers and expiration dates.
6. **Inventory vaccine at least monthly.** Monitoring vaccine inventory will prevent wastage and insure expired vaccine is not being used.
7. Temperature logs must be submitted the Vaccine Center monthly regardless of the need to order vaccines.
8. Providers should follow recommendations and general guidelines for the handling, storage and disposal of vaccines as outlined in the Vaccine Storage Temperature Recommendations (Exhibit E16).
9. Create a safe environment for vaccines:
 - ✓ Instruct custodial staff not to unplug a refrigerator or freezer unit while cleaning; Post “*Do Not Unplug*” (Exhibit E17) signs above the plug, and/or on the refrigeration unit if the unit or other objects obscure the plug.
 - ✓ Post a “*Do not turn off*” or “*Do not unplug*” sign above the surge protector if one is used for the refrigerator or freezer plug.
 - ✓ Protect and mark circuit breaker switches to prevent accidental shut down of power by maintenance and/or repair crews.
 - ✓ If possible, utilize a remote alarm system in case of power failure.
 - ✓ Install **receptacle covers or plug guards** to prevent power loss from accidental unplugging.
 - ✓ Post a red/white “*Caution Perishable Vaccine*” sign (Exhibit E17 - call the Vaccine Center at (602) 364-3642 to order) on the refrigerator and freezer unit where VFC vaccine is stored. Lock storage facilities and equipment to prevent unauthorized removal of vaccine and use of storage for other purposes.
 - ✓ In the event of power failure, **do not open the refrigerator or freezer.** Call the Vaccine Center immediately.
 - ✓ **Store bottles of water in the refrigerator door and alongside the refrigerator wall** (if space permits) to prevent the coils in the walls of the refrigerator from freezing vaccine. This will also assist in maintaining appropriate temperatures in the event of a power/refrigerator failure. Mark these bottles “Do Not Drink.”

- ✓ **Do not store food or drinks in the vaccine refrigerator.** Frequent opening of the door to retrieve food results in temperature fluctuations.

10. For more information on Vaccine Storage and Handling follow the link below to access the CDC Storage and Handling Toolkit.

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

Vaccine Administration

Appropriate vaccine administration is critical to vaccine effectiveness. All persons who administer vaccines should have continuing vaccine administration education and regular skills assessments.

The 6 Rights of Vaccine Administration

Right Patient	⇒ Verify the patient's name, date of birth and vaccine history
Right Medication	<ul style="list-style-type: none">⇒ Check and re-check the labels for both the vaccine and diluent before drawing them up and again before administering vaccine.⇒ Watch out for vaccines with similar names and packaging!
Right Time	<ul style="list-style-type: none">⇒ VFC healthcare providers are expected to comply with the immunization schedule, ages, and intervals established by the ACIP.⇒ The current vaccination schedules can be found online at: http://www.cdc.gov/vaccines/schedules/hcp/index.html
Right Dosage	⇒ Always give vaccine in the dosage recommended by the ACIP. Split or partial doses of vaccine are not valid doses!
Right Route	⇒ Make sure that you are using the route, injection site and needle size indicated for the vaccine being administered.
Right Documentation	<p>The following information must be recorded on the vaccine recipient's permanent record or office file each time a vaccine is administered:</p> <ul style="list-style-type: none">⇒ The type of vaccine.⇒ The vaccine manufacturer and vaccine lot number.⇒ The date the vaccine was administered.⇒ The name, title, office address and signature of the person administering the vaccine.⇒ The VFC/KidsCare eligibility category.⇒ VIS publication date and date the VIS was given to the responsible person.⇒ This information may be maintained in the patient's chart or in a central immunization log, but must be available for review during a VFC Site Visit.

Further information on safe vaccine administration can be found at the CDC vaccine web site at www.cdc.gov/vaccines/recs/vac-admin/default.htm.

Additional VFC Vaccine Administration Guidance

1. Vaccines should be drawn up immediately before administration only.
2. Vaccines should remain in their original boxes until all vials have been used. Open only one box of each vaccine at a time.
3. Vaccines may lose their viability if stored in syringes for any period of time.
4. Vaccines that are not used within the acceptable reconstituted time frames are considered non-viable and must be discarded and accounted for on in *ASIIS/VOMS*. Please reconcile wasted VFC vaccine in *ASIIS/VOMS*.

How to Use Vaccines with Diluents

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluents (liquid) in another. Only use the diluents provided by the manufacturer for that vaccine as indicated on the chart. **ALWAYS** check the expiration date on the diluents and the vaccine. NEVER use expired diluent or vaccine.

Vaccine Name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use*	Diluent storage environment
ActHIB (Hib)	sanofi pasteur	HIB	0.4% sodium chloride	24 hours	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hours	Refrigerator or room temp
MMR II (MMR)	Merck	MMR†	Sterile water	8 hours	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (mulit-dose vial)	Refrigerator
MenHibrix (Hib-MenCY)	GlaxoSmithKline	Hib-MenCY	0.9% sodium chloride	Immediately	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single dose vial) 35 days (multidose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hours	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	HIB	DTaP-IPV	Immediately (i.e, within 30 minutes or less)	Refrigerator
ProQuad (MMRV)	Merck	MMRV†	Sterile water	30 minutes	Refrigerator or room temp

Rotarix (RV1)[‡]	GlaxoSmithKline	RV1	Sterile water, calcium carbonate and xanthan	24 hours	Room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 minutes	Refrigerator or room temp
Zostavax (HZV)	Merck	HZV [§]	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow these steps:

<ol style="list-style-type: none"> 1. For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix[†]), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.[‡] 2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following: <ul style="list-style-type: none"> • that they are the correct two products to mix together • that the diluent is the correct volume (especially for Menomune in the multi-dose vial) • that neither vaccine nor diluent has expired 3. Reconstitute (i.e., mix) vaccine just prior to use[‡] by <ul style="list-style-type: none"> • removing the protective caps and wiping each stopper with an alcohol swab • inserting needle of syringe into diluent vial and withdrawing entire contents • injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder 	<ol style="list-style-type: none"> 4. Check the appearance of the reconstituted vaccine. <ul style="list-style-type: none"> • Reconstituted vaccine may be used if the color and appearance match the description on the package insert. • If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer. 5. If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose Menomune), <ul style="list-style-type: none"> • clearly mark the vial with the date and time the vaccine was reconstituted • maintain the product at 35°–46°F (2°–8°C); do not freeze • protect reconstituted vaccines from light • use only within the time indicated on chart above
<p>* If the reconstituted vaccine is not used within this time period, it must be discarded. [†] MMRV contains seven times as much varicella component as does the single antigen VAR. [‡] Rotarix vaccine is administered by mouth using the applicator that contains the diluent. <u>It is not administered as an injection.</u> [§] HZV contains fourteen times as much varicella component as does the single antigen VAR</p>	

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Note: MMR, MMR-V, HPV, Rota, MCV4 and Varicella are extremely sensitive to light and heat and must be kept in their original boxes with lids closed until ready to use.

Vaccine Loss

By registering as a VFC provider, you have agreed to be accountable for publicly purchased vaccine. Accountability includes documentation procedures and compliance with Arizona VFC Program policies on vaccine loss.

This section will serve as the Arizona VFC Program's policy for management of incidents that result in loss of publicly purchased vaccine. The action taken by the Arizona VFC Program will depend on the cause of vaccine loss: due to non-preventable (beyond the health care provider's control) circumstances, due to negligence, or due to non-compliance (fraud and abuse).

Vaccine Wastage Restitution Policy

Vaccine is purchased through the Centers for Disease Control (CDC) contracts and is distributed to participating VFC providers. As a condition of provider enrollment into the VFC program, providers are required to adhere to Federal Fraud and Abuse laws. These laws apply to the entire VFC program. For more information about Fraud and Abuse requirements, please see chapter 12.

This section of the 2014 Arizona VFC Operation Manual includes the requirements for collecting restitution in certain incidents of vaccine loss. Examples of the most common vaccine loss requiring restitution include:

- ✓ Allowing vaccine to expire before use
- ✓ Not opening vaccine shipments on arrival
- ✓ Leaving the refrigerator or freezer door ajar
- ✓ Not moving vaccine to a backup unit or facility when a refrigerator or freezer is without power or not functioning properly
- ✓ Inability to account for the vaccine in inventory
- ✓ Wasted vaccine due to spillage or being dropped
- ✓ Unreported refrigerator/freezer temperature excursion

AIPO acknowledges that providers make good faith efforts to store and handle vaccines appropriately, as outlined in the manual. However, AIPO will require providers to provide restitution for any doses of federally purchased vaccines that have been lost due to the provider's failure to properly receive, store, account for in inventory or use vaccines if:

- ✓ The total loss is 5% or more based on doses of vaccine shipped during a given quarter (cumulative for each quarter during a calendar year, or
- ✓ This is the 2nd incident (or greater) – regardless of total value, or

- ✓ It is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value or
- ✓ It is due to failure to contact the Arizona VFC program at the first instance of a recorded temperature excursion.
- ✓ Matches Physical Inventory is selected in ASIIS for reconciling VFC vaccine doses.

Restitution will require the provider to purchase private stock vaccine to replace VFC vaccine doses that were lost. Listed below are examples of provider negligence that will require dose for dose restitution of the federally funded vaccine.

- ✓ Failure to open vaccine shipments from McKesson or Merck immediately, resulting in damage to the vaccines.
- ✓ Failure to rotate vaccine stock, resulting in expired vaccine.
- ✓ Allowing vaccine to expire. Providers must contact the Vaccine Center 3 months or more prior to vaccine expiration to arrange a transfer to another VFC provider for usage. If the provider is unable to transfer the doses, they are still responsible for the doses that have expired.
- ✓ Using VFC or KidsCare vaccines for unapproved patients.
- ✓ Freezing vaccines meant to be refrigerated.
- ✓ Refrigerating vaccines meant to be frozen.
- ✓ Refrigerator or freezer left unplugged, or electrical breaker switched off by provider staff, contractors, or any other individual.
- ✓ Refrigerator or freezer door left open or ajar by provider staff, contractors, or any other individual.
- ✓ Vaccine that is left out of the refrigeration unit and becomes non-viable (Always call the Vaccine Center at 602-364-3642 to determine if vaccine can be identified as viable.)
- ✓ Unreported temperature excursions that result in vaccine wastage; providers must contact the Vaccine Center immediately at the first incident of a temperature excursion. No exceptions.
- ✓ Any power outages in which the provider fails to act according to their vaccine storage backup plan.
- ✓ Excessively reporting vaccine in ASIIS as *unaccounted for in provider inventory*
- ✓ Excessively reporting vaccines in ASIIS as *correction of invalid entry*
- ✓ Vaccine lost or damaged in transit between providers.
- ✓ Any other handling and storage mistakes by provider staff.

AIPO will notify the provider concerning the number of doses of each vaccine that must be replaced; vaccine must be replaced on a dose for dose basis. Per CDC requirement, The Arizona Department of Health Services, Immunization Program Office can no longer accept monetary reimbursement for public vaccines. Subsequent

vaccine orders from the provider will not be processed by the Vaccine Center until a copy of the invoice or packing list for the replacement vaccine has been received by AIPO's Vaccine Center. All replacement vaccines must be added to ASIIS showing replacement of the VFC vaccine (choose "restock public inventory from private" from the drop down menu), a copy of the invoice or packing slip should be submitted to the Vaccine Center along with the completed *VFC Dose for Dose Vaccine Replacement* form. (Exhibit 18) These documents must be submitted to the Vaccine Center within 60 days of notification that doses need to be replaced. **These documents can be emailed to arizonaVFC@azdhs.gov or faxed to 602-364-3276.** The documents will then be reviewed, and approved or require additional action.

AIPO recommends that all health care provider offices contact their insurance companies to verify that they have adequate coverage to cover any type of vaccine loss. This coverage should be at a level adequate to cover the private market cost to fully replace the highest level of vaccine inventory that they could potentially maintain in their offices. This coverage should also be evaluated and updated annually as their vaccine formulary changes and the vaccine prices increase.

If the provider receives a wastage replacement statement for the VFC vaccines and wishes to dispute the replacement of public vaccine, the provider must submit, in writing to the Vaccine Center Manager, a letter explaining the reason for the dispute. This letter must include the provider's name, address, and VFC PIN number. Please submit all supporting documentation with the dispute letter so a determination can be made regarding the wastage. Please send this correspondence to the following address:

**Arizona Department of Health Services
Immunization Program Office
Attn : Vaccine Center Manager
150 N. 18th Ave
Ste. 120
Phoenix, AZ 85007**

If a provider receives a replacement statement for wasted vaccines and the provider fails to contact the Vaccine Center Manager to resolve the issue, or a waiver is not granted, doses must be replaced by the specified due date on the replacement statement, if the provider does not replace VFC vaccine doses by the due date, vaccine orders will be held until all doses are replaced.

How to Handle Wasted or Expired Vaccine

1. **Do not discard expired vaccine. Do not send expired or wasted vaccines to the manufacturer.** Remove expired vaccines from the refrigerator or freezer to prevent inadvertent use. Mark the vaccines as expired or wasted so they are not put back into the refrigerator or freezer. These doses ***must be accounted for in your ASIIS/VOMS inventory reconciliation screen.***

You can enter wasted/expired doses into ASIIS/VOMS at any time during the month. Please note, the Vaccine Center will work proactively, to ensure VFC vaccine is tracked and accounted for at all VFC provider offices. If you need technical assistance with this process, please contact the ASIIS hotline at 877-491-5741.

2. Once you have entered the expired and wasted vaccines into ASIIS/VOMS, please contact the Vaccine Center for instructions on how and where to send the vaccine.

Vaccine Returns

VFC vaccines should never be discarded unless providers are told to do so by the Arizona VFC Program. VFC vaccines that have expired, spoiled or wasted should be returned to the CDC central distribution center. Providers must contact the Arizona VFC Program to receive a VFC vaccine return label and to obtain additional information on how to send these vaccines to the distribution center. Vaccines must be returned to the CDC Central Distribution Center within 6 months of spoilage/expiration.

Items to Keep In Mind

- ✓ Every attempt should be made to use VFC vaccine appropriately. If you need assistance with spoiled, wasted or expired VFC-supplied vaccines, contact the Vaccine Center. **Do not call the manufacturer.**
- ✓ **Never administer expired vaccine.** Individuals will remain susceptible to the disease if given an expired, non-viable vaccine and will have to be recalled for revaccination.
- ✓ Vaccines in open multi-dose vials are valid and usable until the manufacturer's expiration date regardless of the length of time since the first dose was withdrawn.
- ✓ If the expiration date is a month and year, the vaccine is valid until the last day of the month (e.g., July 13 is valid until July 31, 2013).
- ✓ All VFC vaccines should be used until the expiration date. In order to ensure vaccines are viable until their expiration date, aseptic technique must be used when withdrawing vaccine from a multi-dose vial. No visible contamination should be present.
- ✓ Monitor vaccine use closely.
- ✓ Inventory your vaccine monthly to check expiration dates.
- ✓ Use vaccines that have the soonest expiration date first.
- ✓ Maintain the "cold chain" and implement vaccine quality controls to ensure vaccine viability and unnecessary loss of vaccine.
- ✓ The only way to protect patients with viable vaccine is to maintain accurate, appropriate and consistent temperatures in your refrigeration units.

When in doubt, call the Vaccine Center at 602-364-3642.

Vaccine Emergency Management Requirements

- ✓ A “review date” is required to verify all plans are current.
- ✓ All plans must include the signature, name, and title of the preparer of the documents.
- ✓ All provider vaccine storage and handling plans must be reviewed and updated annually, or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan.

Emergency Management Plan

Unforeseen circumstances and human error result in vaccines exceeding or falling below recommended temperature ranges. All VFC providers **must** have an established plan for safe vaccine storage during emergencies, e.g., keep vaccines safe and at recommended temperatures during an equipment malfunction, power outage or natural disaster. A *Vaccine Emergency Handling Plan* should be developed for use in every office enrolled in the VFC Program. **The VFC site visit reviewer will ask for a copy of the office vaccine emergency handling plan during compliance visits.** (Exhibit 19)

All staff should review and have a copy of the plan. Post the plan in a highly visible location, such as the door to your vaccine area or on the refrigerator. **All office staff, including the janitor and the security guard, must know what to do and where and how the individual vaccines are to be stored.** It is recommended to have all staff initial the plan to show they have read it.

In the event of equipment breakdown or power outage, **do not open the refrigerator or freezer door until you are ready to move the vaccine(s).** Move the vaccine supply to another refrigerator and freezer unit as soon as possible. Record temperatures of the new unit. Separate the vaccine that may have been stored at improper temperatures from any other vaccine supply and label “*Do Not Use*”. Vaccine should not be used until a VFC representative or the Arizona VFC Program has been contacted for instructions on what to do. Depending on manufacturer specifications, there is a possibility that the vaccine is viable (able to be used). **All spoiled or wasted vaccine supplied by VFC must be returned to the CDC centralized vaccine distributor with 6 months of spoilage/expiration. Never discard VFC vaccine unless instructed to do so by Vaccine Center staff.**

For assistance with spoiled or wasted VFC supplied vaccines, contact the Vaccine Center first at (602) 364-3642.

Chapter 8: VFC PROVIDER COMPLIANCE VISITS

VFC Compliance Visit Requirements

- ✓ All VFC providers must participate in VFC program compliance site visits, including unannounced storage and handling visits and other educational opportunities associated with the VFC program requirements.

The following activities are requirements of the VFC Program and must be conducted by the Vaccine Center staff to ensure the ongoing integrity of the program. These activities include:

Provider Site Visits

1. VFC **compliance reviews** at VFC enrolled provider offices occur every one to two years. The purpose of the visit is to review records in your office and to evaluate VFC eligibility, record keeping, screening, vaccine ordering protocols, and vaccine management which includes storage and handling requirements. The compliance visit is designed to protect against fraud and abuse and observe office practices that:

- ✓ Ensure compliance with VFC program requirements (reporting/documentation/vaccine storage and handling)
- ✓ Minimize vaccine loss and wastage
- ✓ Ensure that vaccines purchased with VFC funds are administered only to VFC eligible children
- ✓ Assure provider profiles are based on real data
- ✓ Ensure VFC Vaccine stewardship and accountability

The VFC program staff are also required to follow up on corrective action plans or improvements received during the VFC compliance site visit.

Note: While every attempt is made to schedule and conduct these visits at a time that will not interrupt office practice, a visit may or may not be pre-scheduled. Each visit takes approximately two to three hours or longer based on information obtained prior to and during the compliance visit.

2. AIPO staff will conduct provider **staff training/education** on VFC program requirements for all newly enrolled providers, new office staff and other staff in need of updates. These visits are scheduled at a time that is mutually agreed upon and will take approximately two to three hours.
3. **Unannounced storage and handling** visits ensure providers are following the current VFC storage and handling requirements

VFC Compliance Requirement

Each provider will also be required to complete a VFC educational training at least once per year. At minimum, the VFC Coordinator and their VFC back up are required to complete this training annually. It is recommended that all staff who handles VFC vaccine complete this training. The training is the CDC web based “You Call the Shots” training module and should be completed at the time of annual re-enrollment into the VFC program. Additionally, all new VFC Coordinators are required to participate in this educational training before they begin handling VFC vaccines. For more information on the “You Call the Shots” Training please review Exhibit 22 in the back of this manual.

VFC Provider Surveys

The Arizona VFC Program conducts a provider satisfaction survey every two years to evaluate the impact of the VFC program on the delivery of immunization services in the public and private sectors. The survey allows the VFC program team to determine if the VFC program is meeting the needs of enrolled providers.

The VFC Program management team also conducts a separate survey related to the provider’s experience with their VFC compliance visit reviewer. Please visit <http://www.surveymonkey.com/s/VFCSurvey> to complete this short survey .

Chapter 9: ASSESSMENTS OF IMMUNIZATION COVERAGE LEVELS (AFIX)

Provider AFIX Assessment

What is AFIX? AFIX is a CDC-designed quality improvement strategy to improve the delivery of immunization services and raise immunization coverage levels

Assessment – of the provider's immunization coverage levels and immunization practice

Feedback – of results to the provider along with recommended strategies to improve processes, practices, and coverage levels

Incentives – to recognize and reward improved performance

Exchange – of information which is also known as follow up with providers to monitor and support quality improvement and improved immunization coverage levels.

More information about AFIX can be found at
<http://www.cdc.gov/vaccines/programs/afix/index.html>

Providers will be notified in advance of the AFIX visit. Prior to the visit, an AFIX specialist will export the immunization records of children 24-35 months of age, and/or those who are 13-18 years of age, from the Arizona Immunization Information System (ASIIS) and import them into the CDC assessment software, CoCASA for analysis. CoCASA reports will be produced to display the immunization coverage levels of your patients. The best and most accurate assessment results are obtained when complete immunization histories of all patients are entered into ASIIS.

What will an AFIX assessment do for your practice? An assessment will:

- Provide you with reports showing the ASIIS-based coverage levels of your patients
- Identify patients who are missing immunizations and specify the doses needed
- Diagnose missed opportunities to immunize and other barriers to immunization delivery
- Present strategies to improve immunization coverage levels
- Identify any invalid vaccine doses
- Present up-to-date provider resource materials
- Provide you with reminder/recall strategies to strengthen coverage levels
- Track your progress through follow up assessments

The AFIX portion of a site visit usually takes less than one hour to complete. If you have questions about the AFIX process or would like to request an AFIX visit, please contact the Arizona VFC Program at 602-364-3642 and ask to speak to an AFIX Specialist.

Chapter 10: PROVIDER REQUEST FOR INACTIVATION OR OFFICE CLOSURE

Voluntary inactivation

Providers may inactivate their enrollment in the VFC program at any time. To prevent wastage of VFC vaccines, providers must notify the Vaccine Center in writing on office letterhead of their intention to inactivate. This will allow time for the provider to transfer VFC vaccines to another VFC provider or return the vaccines to the Arizona VFC Program.

If Vaccine Center staff members are in the area, they will pick-up the vaccine. All vaccines, reporting forms, and equipment supplied by the Vaccine Center, must be returned to the Vaccine Center. Upon dis-enrollment, the provider will be responsible for replacing any vaccine not accounted for or returned in a non-viable state. Additionally all VFC supplied equipment must be returned to the Arizona Immunization Program Office.

Office Relocation, Move or Other Changes

If a VFC office is planning to relocate, the office **must** notify the Vaccine Center **30 or more days prior** to the move. This notice will prevent vaccine wastage due to delivery of vaccine shipments to the wrong location. Five days of refrigerator/freezer temperatures within normal limits must be recorded at the new site prior to transferring the vaccines.

Providers must notify the Vaccine Center of any changes, such as name change, mailing address, shipping address, contact information, email, phone, fax or VFC population changes.

Short-Term Office Closure

Providers should go no more than 4 consecutive days without temperature monitoring. If the provider is out of the office for more than 4 consecutive days, the provider will need to contact the Vaccine Center to arrange for a transfer of the vaccines to another VFC provider office for temporary or permanent storage. Failure to adhere to this requirement will result in the provider replacing doses for any VFC vaccine determined by the Vaccine Center to be non-viable. Upon re-opening the office, temperatures must again be recorded for five consecutive days before VFC vaccine will be shipped/returned to the office.

Chapter 11: DISCIPLINARY PROCESS

Notice of Action Procedures

The Arizona VFC Program is responsible for ensuring that providers meet all VFC program requirements. Failure to comply with Arizona VFC program requirements will result in disciplinary actions. The following program infractions will result in one of the following progressive disciplinary actions. Compliance follow up visits will occur throughout the process.

VFC Corrective Action Process

There are certain corrections that are completed by the VFC site reviewer at the time of the compliance visit. Those findings are documented on the CDC Site Visit Summary form and shared with the provider staff during the visit. Provider staff members are given feedback on items for correction and educated on the importance of the VFC Program requirements. The following are examples of issues that can be resolved during the compliance visit: outdated Vaccine Information Statements (VIS), lack of “Do not disconnect” sign next to storage outlets, missing refrigerator plug guards, or vaccines that have been placed in the back of the unit that will expire soon.

If issues are identified during a VFC site visit that cannot be resolved, the site visit reviewer will try to determine the root cause behind the non-compliance issue. The site visit reviewer will discuss the purpose of the requirement with the VFC Coordinator and/or their backup and educate them on how to be compliant. The VFC site reviewer will provide a timeframe for corrective actions at the time of the site visit. Additional follow up will occur in the form of a letter, phone call, or follow up visit to ensure that corrections were made.

Administrative Observation

Providers will be placed on administrative observation when VFC requirements have not been met after multiple follow ups or an incident has occurred that cannot be corrected on the day of the site visit.

A provider will receive a Corrective Action Plan from the site visit reviewer specifying the needed areas of compliance and notification of a follow up visit at the end of the administrative observation period.

All instances of Administrative Observation will be reported to AHCCCS.

Reasons a provider could be placed on administrative observation include:

- ✓ Administering VFC vaccine to ineligible children, for example, children who have private insurance that covers vaccine;
- ✓ Administering VFC vaccine to inappropriate age groups, for example, persons 19 years of age and older;
- ✓ Failing to provide patients with current VISs for each vaccine administered;
- ✓ Failing to maintain vaccine storage and handling requirements;
- ✓ Failing to record refrigerator and freezer temperatures twice daily during the work week;
- ✓ Failing to replace a broken thermometer;
- ✓ Failing to send in temperature logs
- ✓ Failing to record and report the following to the Vaccine Center:
 - Vaccine inventory
 - Correct VFC eligibility data in ASIIS
- ✓ Failing to report administered immunizations to the Arizona State Immunization Information System (ASIIS) within 30 days;
- ✓ Failing to record the vaccine lot number, manufacturer, administration site, and immunization administrator name on the administration record;
- ✓ Storing Varicella or MMR-V in an unapproved freezer;
- ✓ Pre-drawing vaccine and/or storing it in the syringe;
- ✓ Failing to report out of range temperatures to the Vaccine Center.
- ✓ Failing to comply with issues discovered during a site visit and written into a corrective action plan.
- ✓ Failing to screen patients for VFC eligibility;
- ✓ Failing to provide vaccines to VFC eligible children when VFC vaccines are available;
- ✓ No private vaccine supply is found at the provider site when records indicate privately insured children are seen at this site;
- ✓ Billing VFC eligible patients more than the current allowable administration fee of \$21.33.
- ✓ Administering expired vaccine.
- ✓ Administering vaccine in incorrect dosages based on ACIP and manufacturer's recommendations.
- ✓ Vaccine borrowing that indicates an inventory/stock problem;
- ✓ Denying administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

Administrative Observation will end when the VFC site reviewer has observed substantial improvement by the provider.

Inactivation

Inactivation occurs when the provider has failed to adhere to VFC requirements after multiple attempts by the VFC program staff to correct non-compliance issues or for the following reasons:

- ✓ Any complaint of fraud and abuse that is substantiated;
- ✓ Failure to comply with the terms of the VFC Program enrollment agreement
- ✓ Provider's name appears on the Exclusions Database of the Department of Health and Human Services, Office of Inspector General;
- ✓ Provider is not currently licensed or in good standing by any Arizona State Board governing their practice;
- ✓ Failure to submit annual re-enrollment forms;
- ✓ Failure to become program compliant while on administrative observation;
- ✓ The Vaccine Center receives the provider's written, voluntary request for disenrollment from the program.

All inactivations will be reported to AHCCCS.

Note: All administrative actions implemented by the Arizona VFC Program are reported to AHCCCS. Since AHCCCS enrolled providers must be enrolled in the VFC program, inactivation from the VFC Program will result in the provider losing the privilege of being an AHCCCS provider for children birth through 18 years of age.

Chapter 12: VFC VACCINE FRAUD AND ABUSE

As the cost of childhood vaccines increases and the complexity of immunization programs grow, the VFC program becomes more vulnerable to fraud and abuse. Federal fraud and abuse laws apply to the VFC program. In addition, for those providers administering KidsCare vaccines, state fraud and abuse/consumer protection/medical licensure laws may also apply. Consistent with “fraud and abuse,” as defined in the Medicaid regulations at 42 CFR §455.2, for the purposes of this Arizona VFC Operations Guide, the following definitions will be used:

Definitions/ Relevant Terms:

Fraud is defined as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse is defined as activities that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, [and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient]; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes activities that result in unnecessary cost to the Medicaid program.

Oversight the Arizona VFC program will ensure that federally funded VFC vaccines are administered, recorded, stored and handled appropriately according to VFC requirements through compliance visit reviews, monitoring VFC vaccine ordering practices and inventory reconciliation as well as unannounced storage and handling visits. These areas will be monitored and checked regularly for all providers enrolled in the VFC program.

Enforcement is the Arizona VFC program’s responsibility to ensure all providers adhere to current VFC requirements. If it is found that VFC providers are intentionally misusing federally funded VFC vaccines, disciplinary steps will be taken to ensure immediate correction.

Enforcement Actions for Fraud and Abuse

The Arizona VFC program will formally investigate all instances of possible fraud and abuse on a case-by-case basis to differentiate between intentional fraud and abuse and unintentional abuse or error due to excusable lack of knowledge.

If you have not met Arizona VFC requirements or followed Arizona VFC procedures as outlined in this manual, but the Arizona VFC program finds no intentional deception, misrepresentation, or negligence on your part, you may be required to participate in training and/or to take other actions to rectify the situation.

If the Arizona VFC program finds evidence of intentional deception, misrepresentation, or negligence on the part of the VFC provider, further investigation will occur and relevant laws will be enforced. Laws that may be enforced include, fraud and abuse, consumer protection, and professional licensure.

Examples of Fraud and Abuse

- ✓ Providing VFC vaccine to non-eligible children;
- ✓ Selling or otherwise misdirecting VFC vaccine;
- ✓ Billing a patient or third party for VFC vaccine;
- ✓ Charging more than the established maximum regional rate (in Arizona, the rate is \$21.33) for administration of a VFC vaccine to a federally vaccine eligible child;
- ✓ Not providing VFC eligible children VFC vaccine because of parents' inability to pay the administration fee;
- ✓ Not implementing provider enrollment requirements of the VFC program;
- ✓ Failing to screen patients for VFC eligibility;
- ✓ Failing to maintain VFC records and comply with other requirements of the VFC program;
- ✓ Failing to fully account for VFC vaccine;
- ✓ Failing to properly store and handle VFC vaccine;
- ✓ Ordering VFC vaccine in quantities or patterns that do not match the provider profile or otherwise involve over-ordering VFC vaccines;
- ✓ Wastage of VFC vaccine.

Chapter 13: VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. The information from the VAERS report is added to a VAERS data bank which is further analyzed to look for trends or suggestions of potential vaccine safety concerns.

Reporting to VAERS

Who can file a VAERS report: Anyone can submit a VAERS report. This includes healthcare providers, vaccine providers, public health officials, vaccine manufacturers and persons vaccinated or their caregivers.

What adverse events should be reported: VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. Report such events even if you are unsure whether a vaccine caused them. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- ✓ Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- ✓ Any event listed in the VAERS Reportable Events Table that occurs within the specified time period after vaccination.

A copy of the Reportable Events Table can be obtained by calling VAERS at 1-800-822-7967 or by downloading it from

http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Filing a VAERS Report

VAERS reports may be filed in three ways: securely online, by mail, or by fax. VAERS report forms are available online at <http://www.vaers.hhs.gov> or can be obtained by calling 1-800-822-7967. Please visit the VAERS website for further information and instructions.

Additional VAERS Information

- ✓ Send e-mail inquiries to info@vaers.org
- ✓ Fax inquiries to the toll-free information fax line at (877) 721-0366
- ✓ Call the AZ Vaccine Center at 602-364-3642

This information has been adapted from the VAERS website <http://www.vaers.hhs.gov>

Chapter 14: THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) was enacted on August 21, 1996. Provisions of the act that apply to health care providers took effect April 14, 2003. A simplified description of some of the provisions follows:

The U.S. Department of Health and Human Services (DHHS) recognized the importance of sharing Protected Health Information (PHI) to accomplish essential public health objectives and to meet certain other social needs (e.g., administration of justice and law enforcement). Therefore, the Privacy Rule expressly permits PHI to be shared for specified public health purposes. For example, covered entities may disclose PHI, without individual authorization, to a public health authority legally authorized to **collect or receive the information for the purposes of preventing or controlling disease**, injury or disability [**45 CFR §164.512(b)**]. Further, the Privacy Rule permits covered entities to make disclosures that are required by other laws, including laws that require disclosures for public health purposes.

The full document is available at <http://www.hhs.gov/ocr/privacy/>.

Chapter 15: CONTACTS AND RESOURCES

Directory of Arizona VFC and AFIX Staff

VFC Mailing Address: Arizona Immunization Program Office
Vaccine Center
150 N. 18th Avenue, Suite 120
Phoenix, Arizona 85007-3233

Telephone: (602)-364-3642

Fax: (602)-364-3276

Web Site: http://www.azdhs.gov/phs/immun/act_aipo.htm

VFC Managers: **Tiffany R. McRae, M.S.**
Vaccine Center Manager
Office: (602) 364-3644
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tiffany.mcrae@azdhs.gov
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All counties

Michelle L. Hanson, MPH, RN
Special Programs Manager
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All counties

VFC Representatives: **Faith Herbert**
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Teresa Saenz
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Vaccine Ordering Team: **Rosita Davis**
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Zachary Guzman
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AFIX Specialist

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Fax: (602) 364-3285

AFIX Specialist

Melissa Murrieta

Tucson office

Southern Arizona

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Fax: (520) 770-3307

**VFC Administrative
Assistant**

Debra Dill

Phoenix Office

Debra.dill@azdhs.gov

Office: 602-364-3642

Fax: 602-364-3276

Additional Resources for VFC Providers

State:

Arizona Vaccines for Children (VFC) Program

<http://azdhs.gov/phs/immunization/vaccines-for-children/> Phone: 602-364-3642 Fax: 602-364-3276

Arizona State Immunization Information System (ASIIS)

<http://www.asiis.state.az.us>

<http://www.azdhs.gov/phs/asiis/>

Hotline: 1-877-491-5741

Federal:

Vaccines and Immunizations

www.cdc.gov/vaccines/

Federal Vaccines for Children (VFC) Program

<http://www.cdc.gov/vaccines/programs/vfc/index.html>

Advisory Committee on Immunization Practices (ACIP)

<http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>

CDC-Morbidity and Mortality Weekly Report (MMWR)

www.cdc.gov/mmwr/

Local/National Immunization Organizations:

The Arizona Partnership for Immunization (TAPI)

<http://www.whymmunize.org/>

Immunization Action Coalition (IAC) provides Vaccine Information Statements (VIS) in a number of languages at <http://www.immunize.org/>

National Institute for Standards and Technology

<http://www.nist.gov/index.html>

Vaccine Manufactures:

Merck

<https://www.merckvaccines.com/is-bin/INTERSHOP.enfinity/WFS/Merck-MerckVaccines-Site>

MedImmune

<http://www.medimmune.com/Default.aspx>

GSK

<http://www.gskvaccines.com/>

Novartis

<http://www.novartisvaccines.com/>

Pfizer

<http://www.pfizer.com/home/>

Sanofi Pasteur

<https://www.physall.com/sanofi-pasteur-vaccines-public>

References

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2. Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th Edition, Centers for Disease Control and Prevention, May 2012.
<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
3. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), January 28, 2011.
4. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention (CDC). “Vaccine Storage and Handling Toolkit.” November 2012.
5. Committee on Infectious Disease, American Academy of Pediatrics, Red Book, 29th Edition, American Academy of Pediatrics, 2012.
<http://aapredbook.aappublications.org/content/current>

Exhibits